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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,247	07/09/2003	Philip S. Kim	DRPK-0003	9491
23377	7590	03/23/2006	EXAMINER	
WOODCOCK WASHBURN LLP ONE LIBERTY PLACE, 46TH FLOOR 1650 MARKET STREET PHILADELPHIA, PA 19103			STIGELL, THEODORE J	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 03/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/616,247

Applicant(s)

KIM, PHILIP S.

Examiner

Theodore J. Stigell

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>8/21/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

In response to the Applicant's traversal filed on February 7, 2006, the Examiner agrees with the Applicant and has withdrawn the Restriction Requirement. Claims 1-31 were examined on the merits in this Office Action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Xavier (5,458,631). Xavier discloses an implantable catheter and pump used for long term pain management comprising a surgically implanted catheter (12) having a discharge portion (30) that is capable of lying in a neural structure peripheral to a central nervous system and an implantable pump (32) and reservoir (38) located in a subcutaneous tissue, wherein a proximal end of the catheter, and the reservoir, are in fluid communication with the pump and the pump is operated to deliver a predetermined dosage of medication through the discharge portion into the peripheral neural structure, thereby alleviating pain and providing pain management and wherein the catheter has an embedded and electrically conductive material (14) throughout the catheter length sufficient to enable electrical conduction, the material facilitating stimulation to verify a catheter distal end location adjacent to the neural structure.

Claims 28 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Galindo (4,411,657). Galindo discloses a surgical needle for use in inserting a catheter comprising an electrically conductive shaft (14) having a first end (16) adapted to enter a facial sheath of a neural structure, a second end, wherein the shaft has an interior channel running longitudinally there through, and an electrically conductive protrusion (30) extending from the shaft to create a corner there between, the protrusion facilitating connection to a clip located at the distal end of a nerve stimulator.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xavier (5,458,631). Xavier discloses the invention as substantially claimed. Xavier does not disclose the specific medication or the amount of medication to administer to the patient. However, these parameters are deemed matters of design choice, well

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within the skill of the ordinary artisan, obtained through routine experimentation in determining the results.

Claims 1-21 and 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein et al. (Anesth Analg 2000; 91:1473-1478) in view of Xavier (5,458,631). Klein et al. disclose a method of providing long term pain management that includes most of the limitations as recited in claims 1-21 and 30-31, including surgically implanting a catheter to create an infusion site, wherein a discharge portion of the catheter lies in a peripheral neural structure, attaching a pump to the catheter and operating the pump to deliver a predetermined dosage of medication through the discharge portion of the catheter into the infusion site. However, Klein et al. teach to use a disposable infusion pump to deliver the drugs instead of an implantable infusion pump.

Xavier discloses an implantable catheter and pump that provides long term pain management by infusing drugs into the epidural space of the patient. Xavier teaches to use a permanently implantable pump to reduce damage to the patient's skin and to reduce the risk of infection.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Klein et al. with the implantable pump of Xavier to make a method that was less prone to cause damage or infection to the patient.

Conclusion


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Stigell whose telephone number is 571-272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Theodore J. Stigell


NICHOLAS LUCCHESI
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